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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,344	08/14/2006	Vaddu Venkata Narayana Reddy	U 015836-6	8104
140	7590	11/12/2008		
LADAS & PARRY LLP 26 WEST 61ST STREET NEW YORK, NY 10023			EXAMINER KATAKAM, SUDHAKAR	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 11/12/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,344

Applicant(s)

REDDY ET AL

Examiner

Sudhakar Katakam

Art Unit

1621

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the application

1. Receipt of Applicant's remarks and arguments filed on 11th Aug 2008 is acknowledged.
2. In view of the applicants' cancellation of claims 1-44, the previous rejections have been withdrawn.
3. However, upon further consideration, in view of applicants' new set of claims, a new ground(s) of rejection is made in view of different interpretation of the previously applied reference, newly found prior art references, and provide an explanation of the rejection.
4. Claims 1-44 have been cancelled.
5. Claims 45-81 have been added as new claims.
6. Claims 45-81 are discussed on the merits in this action.

Claim Objections

7. Claims 66 and 75 objected to because of the following informalities: In the claims 66, the "AS" should be changed to "A". In the claim 75, line 3, the word "form" should be changed to "from". Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 45-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Masahiro et al** (IDS 8/14/06 AN - Abstract of JP 55-136245, full translation is pending) in view of **Takuma et al** (IDS 8/14/06 AM - EP 0 107 972 A1) and **Yoneyoshi et al** (US 5,510,519).

Masahiro et al teach optical resolution of alpha-isopropyl-p-chlorophenylacetic acid (+)-or-(-)(ICPA), ICPA is also known as (\pm)-2-(4-chlorophenyl)-3-methyl butanoic acid (CPA), using optically active alpha-phenyl-beta-p-tolyl-ethylamine (PTE) or optically active alpha-phenylethylamine (PEA) comprises (i) reacting (+)-or-(-)(ICPA) with optically active PTE or optically active PEA in mixed solvent consisting of hydrophobic organic solvent, hydrophilic organic solvent and/or water, to selectively precipitated salt of optically active ICPA; (ii) separating crystals from the mother liquor; (iii) purifying crystals in mixed solvent of organic hydrophobic solvent, and organic hydrophilic solvent and/or water; and (iv) decomposing salt to obtain optically active ICPA. Optical purity of (+)ICPA is increased by use of the described solvent.

The difference between the instant claims and the abstract of **Masahiro et al** is that the abstract is silent on cooling the resultant mixture comprising crystallized salt,

the concentrations of reactants, temperature range of the reaction conditions, recovering (-)-CPA using the solvent system, selected from dichloromethane, dichloroethane, chloroform, toluene and hexane, and recovery of resolving agent. However, **Takuma et al** and **Yoneyoshi et al** cure these deficiencies.

Takuma et al, in an analogous process, disclose a method for optical resolution of alpha-isopropyl-p-chlorophenylacetic acid (ICPA), also known as (\pm)-2-(4-chlorophenyl)-3-methyl butanoic acid (CPA), by using an optically active alpha-phenyl-beta-(p-tolyl)ethylamine (PTE) as an optical resolving agent [page 1, lines 1-8]. First, ICPA is reacted with (+)-PTE to form a salt. The amount of (+)-PTE is in a range of 0.5 to 1.0 mole based on 1 mole of ICPA [page 6, lines 12-14]. The temperature for the reaction is 40°C to 150°C. Next, the ICPA-PTE salt is crystallized in the solvent. The solvents are selected from lower alcohols, lower aliphatic ketones, mixtures with aromatic hydrocarbons, solvents may be used in a mixture with water, and the amount of solvent is preferably 1 to 15 times by weight [page 7, lines 5-22]. A temperature of crystallization is carried out at 0°C to 60°C. Next the crystallization salt crystal is separated from the mother liquor by means such as filtration. The crystal salt is preferred to decompose the salt into (+)-ICPA by acid (e.g. HCl, sulfuric acid) or alkali [page 8, lines 1-9]. When (-)-ICPA of high optical purity is required, this object can be attained by carrying out completely the same operation using (-)-PTE of not less than 95% in optical purity. **Takuma et al** also acknowledge that alpha-phenylethylamine is used as an optical resolving agent form ICPA [page 1, lines 21-23]. **Takuma et al** also

teach wide variety of solvents for the isolation of (+)-ICPA and (-)-ICPA, which include toluene, chloroform, and can be mixed with water etc. [page 7, lines 8-21].

Yoneyoshi et al, in an analogous process, teach the recovery of resolving agent in the process for producing optically active carboxylic acid by using amine as a resolving agent. The crystalline material is separated by filtration, and decomposed with an acid such as hydrochloric acid, sulfuric acid, thereafter; an extraction operation is carried out with organic solvent to give optically active carboxylic acid. On the other hand, the aqueous layer is alkalinized and subjected to an extraction operation, whereby the (R)- or (S)-isomers of optically active amine compounds may be easily recovered for the reuse thereof [col. 5, lines 22-45]. **Yoneyoshi et al** also teach the use of hydrocarbon solvents for the process for producing optically active carboxylic acid using an amine as a resolving agent [col. 5, lines 10-15].

In summary, **Masahiro et al** teach optical resolution of alpha-isopropyl-p-chlorophenylacetic acid (+)-or-(-)(ICPA) using optically active alpha-phenyl-beta-p-tolylethylamine(PTE) or optically active alpha-phenylethylamine (PEA). **Takuma et al** teach aryl amines as resolving agents for preparing (+)-ICPA and (-)-ICPA from (\pm)-ICPA using hydrophilic and hydrophobic or mixtures thereof. **Yoneyoshi et al** teach the recovery of resolving agents such as aryl amines in the process for producing optically active carboxylic acids.

The claims would have been obvious because, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads

to the anticipated success, it is likely the product, not of innovation, but of ordinary skill and common sense.

The claims would have been obvious because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner.

All the claimed elements were known in the prior art and one skilled person in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to have yielded predictable results to one of ordinary skill in the art at the time of the invention.

The Supreme Court in KSR noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then the resulting invention would have been obvious because one of ordinary skill could not have been expected to achieve it.

Therefore, in view of explicit teachings of references, the examiner asserts that it would have been obvious to a person of ordinary skill in the art, at the time of the invention was made, to have combined the teachings of references to make (+)-2-(4-chlorophenyl)-3-methyl butanoic acid (also known as alpha-isopropyl-p-chlorophenylacetic acid) with a reasonable expectation of success.

Some limitations in the present dependent claims may not be expressly taught in the cited prior art. However, these limitations appear to be drawn to tweaking the

composition conditions, particularly concentration ranges, temperature ranges, reaction time etc. Modifying such methodology is prima facie obvious because an ordinary artisan would be motivated to use reaction conditions from the known processes to make the optically active compound more efficient or explore economical advantages over the other, since it is within the scope to optimize the conditions through routine experimentation. Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

12. No Claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karl J. Puttlitz/

Primary Examiner, Art Unit 1621